the results did not cause an added value of the drug in this respective application. In seven cases the indirect comparison was declined due to a different comparator as determined by the G-BA. Three indirect comparisons were declined because of methodological deficiencies and another three indirect comparisons were declined because non-adjusted indirect comparisons were performed. **CONCLUSIONS:** The IQWiG only accepts adjusted indirect comparisons. The application of the correct methodology is necessary to gain valid results and shall not be questioned. The IQWiG approach is accurate with regard to contents and correct in a legal sense. However the procedure shows, that the external preconditions and methodological requirements are demanding and almost impossible to fulfill. Main reason for denial is the divergence from the prespecified appropriate comparator set by the G-BA. To get back to the original aim of the early benefit assessment, a more realistic and reasonable determination of the appropriate comparator would be desirable.

PHP189
THE ADOPTION OF HEALTH TECHNOLOGIES: A SURVEY OF BRAZILIAN POLICY MAKERS
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OBJECTIVES: Policy makers of municipalities decided to adopt health technology into the Brazilian Public Health System (SUS). This group met during national conferences. The last conference, "The XXVIII National Congress of Municipal Health Secretariats (CONASEMS)", took place during June 11 to 14, 2012. The aim was describe the views of participants at the CONASEMS event regarding technology assessment criteria for the Brazilian Public Health System (SUS). **METHODS:** A survey applied at the Ministry of Health's exhibition booth, June 11 to 14, 2012. Three variables were studied for the survey: "Participant Profile", "Knowledge of Health Technology Assessment for Adoption by the SUS" and pre-selected criteria for assessing health technologies (where 1=most important and up to 9=least important) **RESULTS:** The survey encompassed 5.6% (244/4.328) of all conference participants. Of these, 43% represented policy makers; 35% health professionals and 22% others. Of the total amount of participants, 67% have little or average knowledge of HTA and 14% declared having no knowledge of the area. The values in the adoption of health technologies were ranked by delegates. The score of one was: evidence on patient safety, improved quality of life and patient survival, impact on the population's health. The score nine was: relationship between benefits and costs, health system costs and patient costs. **CONCLUSIONS:** Considering the results, the value related to criteria regarding quality of life and survival were the most important in detriment to cost criteria. It is important to involve the Brazilian Network for Health Technology Assessment (REBRATS) as an additional contribution to the application of the new Brazilian law regarding the incorporation of health technologies.

PHP190
ORPHAN DRUGS IN THE GERMAN EARLY BENEFIT ASSESSMENT– REAL WORLD VERSUS G-BA BUREAUCRACY
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OBJECTIVES: Early benefit assessment pursuant to AMNOG was introduced to cut costs and illustrate the additional benefit of new pharmaceuticals including orphan drugs at launch in Germany. In this process orphan drugs have a special status. The EMA orphan drug designation implies the assumption that at least a not-quantifiable additional benefit is set by law. However the extent of the additional benefit still has to be demonstrated by the manufacturer. **METHODS:** By June 2013 seven orphan drug dossiers have been submitted and assessed. Only one product has been admitted an important additional benefit. Four substances had a minor additional benefit and two substances had a not-quantifiable additional benefit. **RESULTS:** An additional benefit needs to be proven against a comparator. But the G-BA will not define an appropriate comparator as for non-orphan drugs. Instead, the assessment of orphan drugs is based on the pivotal trial; the comparator will be derived from this trial. Due to the early phase of pivotal trials in rare diseases, using a comparator is not common. Furthermore, phase II trials often do not meet requirements in terms of evidence level requested: randomized controlled trials with large patient populations are unusual in orphan diseases as well as investigation of valid patient relevant endpoints or validated surrogate endpoints. **CONCLUSIONS:** The G-BA requirements for HTA assessments are drawn from phase III trials and demonstration of an additional benefit over an appropriate comparator, which also serves as price benchmark. The requirements derived for all newly launched products do not reflect orphan drug reality, which is indication and not agent based. In summary the EMA declaration of early admission of orphan drugs in phase II conflicts with the G-BA's methodological requirements for the quantification of an additional benefit. In fact, manufacturers of orphan drugs face an additional barrier before launch in Germany.

HEALTH CARE USE & POLICY STUDIES – Population Health

PHP191
VARIATIONS IN THE HEALTH STATUS OF IRISH REGIONS
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OBJECTIVES: This paper constructs a composite index that is sufficiently comprehensive to rank the overall health status of Irish regions and sufficiently detailed to identify the principal sources of varying regional health status. **METHODS:** We draw on the CSO (Central Statistics Office), PCRS (Primary Care Reimbursement Service) and IPH (Institute of Public Health) health and medicines databases to construct a composite index of the health status of the 8 HSE regions in Ireland in 2010. Our composite health index (CHI) has 6 component indices. Each maps the regional prevalence of major health conditions for which an ATC (Anatomical Therapeutic Classification) group of drugs was prescribed. Our composite health index, CHI, is a coverage-weighted average of the separate indices we construct for persons covered by each community drug scheme in each region. **RESULTS:** Respiratory health status varies most across Irish regions but Cardiovascular, Central Nervous System and 'Other' health conditions have higher CHI weights and contribute more to overall regional health disparities. The Midlands region had the poorest health status in 2010 (8% below the national average); the Eastern region had the best (6% above average), followed closely by the Mid-West. The Mid-West has a better health status than the Midlands despite having lower income and a larger elderly population share. The health status of the Eastern region is just 2% higher than the Mid-West even though its income is 6% higher and the percentage of its population aged over 65 is 1.8 percentage points lower. Simple economic and demographic variables - mean income and the elderly population share – correlate well with health status. **CONCLUSIONS:** Our index maps significant regional disparities and paves the way for complementary epidemiological studies to trace their underlying lifestyle and medical causes and inform regional health policy.

HEALTH CARE USE & POLICY STUDIES – Prescribing Behavior & Treatment Guidelines

PHP192
FEASIBILITY OF MEDICINES REVIEW TO REDUCE POTENTIALLY INAPPROPRIATE MEDICINES IN THE ELDERLY: THE OPTI-SCRIPT CLUSTER RANDOMIZED CONTROLLED TRIAL
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OBJECTIVES: Potentially inappropriate medicines (PIMs) can result in increased morbidity, adverse drug events and hospitalizations. Polypharmacy is the strongest predictor of PIMs,the prevalence of which was 36% in 2007 in those aged ≥ 70 years , with an associated expenditure of over €45 million. Medicines review may have the potential to improve patient outcomes and reduce prescribing costs. This study aims to assess the feasibility of introducing medicines review to reduce PIMs in older patients. **METHODS:** OPTI-SCRIPT is a cluster randomized controlled trial (RCT), that aims to assess the effectiveness of a complex intervention incorporating academic detailing, a medicines review with web-based pharmaceutical treatment algorithms that provide recommended alternative treatments, and tailored patient information leaflets in reducing PIMs. A qualitative evaluation is being conducted to determine the feasibility and acceptability of the intervention. **RESULTS:** Twenty-one GP practices (response rate 32.3%) participated. Identifying patients with a PIM required considerable time and expertise. Practices screened all patients aged ≥ 70 years to identify those suitable to participate. A pharmacist reviewed their repeat medications, identifying patients with a PIM who were then invited to participate. Despite being offered a once off review of their current prescriptions with their GP, only 37.4% (196) agreed to participate. Preliminary qualitative findings indicate that intervention group GPs valued the review process as an opportunity to reflect on their prescribing practice. Some GPs highlighted that conducting routine structured reviews with older patients wouldn't be feasible due to the time, resources and funding available to them currently in primary care. Participating patients placed a high value on their medicines review. **CONCLUSIONS:** Preliminary findings illustrate that implementing a system of structured reivews for older patients with a PIM is challenging. However, participating GPs and older patients saw the value of conducting medicines reviews, but formal resourcing of such services would need to be considered.

PHP193
USE OF CLINICAL PRACTICE GUIDELINES BY PHYSICIANS IN JAPAN
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OBJECTIVES: The present study aimed to determine the proportion of physicians in Japan who use clinical practice guidelines, as well as factors influencing this choice. **METHODS:** We conducted an on-line cross-sectional survey throughout Japan on general internists, gastroenterologists, cardiologists, endocrinologists and general surgeons, including gastrointestinal or breast surgeons, who registered for marketing research. Questions addressed their usage of CPGs in practice, education, and research, as well as their attitudes toward CPGs. We then investigated associations between usage and characteristics of the respondents. **RESULTS:** We received responses from 1342 physicians, 1222 (91.1%) of whom were male (mean age (SD), 46.5 (9.6) years). The proportion of respondents who always or often use CPGs in several practice settings, such as when providing explanations to patients based on CPGs, ranged from 27.7% to 54.6%. Among them, 822 respondents (61.3%) applied 1 to 4 CPGs, and 381 (28.4%) applied 5 to 9. Usage differed according to age group, subspecialty, and workplace. After multivariate adjustment, the mean probability (95% confidence interval) of a high usage of CPGs when providing explanations to patients was 65% (60% - 71%) and 40% (30% - 50%) for those aged < 40 y and ≥ 60 y, respectively, 44% (38% - 50%) for general internists, 65% (59% - 71%) for surgeons, and 51% (46% - 57%) and 65% (58% - 72%) for those working in clinics and university hospitals, respectively. Attitudes towards the trustworthiness and convenience of CPGs were associated with usage, although this was unable to explain all differences in usage among subgroups. **CONCLUSIONS:** A substantial proportion of Japanese physicians use CPGs in clinical practice. Age, subspecialty, and workplace were independently associated with CPG usage. This should be considered during the process of CPG implementation.

PHP194
SYSTEMATIC REVIEW ON USE OF ECONOMIC EVIDENCE BY CLINICAL GUIDELINES
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OBJECTIVES: The recent reforms and policy changes have increased the cost pressures on all health care stakeholders, including clinical experts. In the past, clini-

cal guidelines were developed independent of cost or economic considerations. However, increasingly, more clinical guidelines are mentioning cost concerns and referring to economic data in new recommendations. The objective of this study was to analyze trends in the use of health economic information for developing clinical guidelines. **METHODS:** To understand trends in use of health economic information we conducted targeted search for clinical guidelines, expert recommendations, and consensus statements with specific mention of "cost" or "economic" or related terms. A systematic literature search was undertaken for the databases Pubmed, Google Scholar and Cochrane. The guidelines published between 2003-2012 were included. For guidelines which met the search criteria, data was collected for the name of the authors, indication, year of publication, country/region, and context of use of cost/economic evidence. **RESULTS:** Sixteen clinical guidelines published between 2003-2012 met the inclusion criteria for specific mention of cost/economic evidence. More than 50% of these guidelines were published between 2006-2012. For indication, 3 out of 16 guidelines were for diabetes, while the rest were for different indications. In these 16 guidelines "cost effectiveness" was mentioned 14 times, either referencing cost-effectiveness data or to mention the importance of such data for selecting treatment options. The guidelines commonly cite high cost of disease or high economic burden as one of the considerations for developing new recommendations (11 out of 16). Another term that was commonly used by these guidelines was "cost-benefit," which was mentioned 5 times in these guidelines. Notably, QALY was rarely mentioned (1 out of 16 times) in these guidelines. **CONCLUSIONS:** This analysis suggests that some clinical experts groups are increasingly showing willingness to use and incorporate health economic information for developing new recommendations.

PHP195

REASONS GIVEN BY THE EUROPEAN MEDICINES AGENCY FOR REVISING DISEASE-SPECIFIC SCIENTIFIC GUIDELINES

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OBJECTIVES: To review all the reasons provided by the European Medicines Agency (EMA) to substantiate the need for revisions to or updates of disease-specific scientific guidelines developed by the Committee for Medicinal Products for Human Use (CHMP). **METHODS:** All the scientific guidelines issued by the CHMP were reviewed on the EMA's website. The guidelines not focusing on disease-specific issues were not selected, i.e., guidelines listed in the following sections: Clinical Pharmacology and pharmacokinetics, General, Herbal Medicinal products, Information on medicinal products, and Radiopharmaceutical and diagnostic agents. **RESULTS:** A total of 182 disease-specific scientific guidelines were reviewed. The review identified 21 concept papers developed with the intent of revision (11.5% of specific guidelines). The analysis of the concept papers revealed that four main reasons were claimed: 1) Clarifications needed for pediatric development [10 concept papers: acute heart failure, asthma, Crohn's disease, hepatitis C, hypertension, glucocorticoid-induced osteoporosis, irritable bowel syndrome (IBS), multiple sclerosis, pain, and ulcerative colitis); 2) Evolution in the field and treatments (n=9); 3) Clarifications on endpoints identification and measurement (n=7); and 4) Safety aspects (n=6). For instance, in asthma, one of the critical aspects to be discussed regarding endpoints was "*the need to reinforce the use of clinical measurements (symptoms) and patient-reported outcome measures to complement lung-function parameters*." In IBS, regulators asked that "An evaluation whether more clear recommendations as regards the use of certain scales or newly developed PROs can be made is also desirable." **CONCLUSIONS:** The main reason for the EMA to revise disease-specific guidelines is the need for providing guidance in pediatric issues. This is in line with the introduction of Pediatric Investigation Plans (PIPs) by the European Commission in January 2007 to help ensure that medicines for children are included in the mainstream drug development process in Europe.

HEALTH CARE USE & POLICY STUDIES – Quality of Care

PHP197

REDUCTION IN FIXATION TIME AND RELATED SURGICAL STRESS WITH THE USE OF ETHICON SECURESTRAP™ OPEN ABSORBABLE STRAP FIXATION DEVICE IN THE DEPLOYMENT OF INTRA-PERITONEAL ONLAY MESH (IPOM) FOR OPEN VENTRAL HERNIA REPAIR

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OBJECTIVES: This study compared fixation time using ETHICON SECURESTRAP™ Open device to suture fixation of IPOM mesh in ventral/ incisional hernia repair. It also assesses surgeon-reported levels of task load experienced during the two fixation approaches. **METHODS:** Nine surgeons inserted skirted mesh using IPOM technique on created incisional defects in live swine models. Each surgeon performed two suture (using their standard technique) and two ETHICON SECURESTRAP™ Open fixation procedures. The duration of fixation procedure starting from mesh preparation through the last firing or suture knot was recorded. Surgical workload was measured using the validated Surgery Task Load Index (SURG-TLX) questionnaire. Time savings and task load reduction were determined by the lower limit of the two-sided 95% confidence interval for the difference between suture fixation and ETHICON SECURESTRAP™ Open groups. **RESULTS:** A total of 38 IPOM fixation procedures were performed with equal numbers using suture and ETHICON SECURESTRAP™ Open. 89% reduction in mean fixation time was observed from suture to mechanical fixation with ETHICON SECURESTRAP™ Open [mean reduction: 34.9 minutes (SD: 17.9 minutes); p<0.0001]. Similarly, 55% reduction in perceived overall workload was observed with SECURESTRAP™ Open compared to suture fixation [mean reduction: 22.17 (SD: 15.12); p=0.0003]. ETHICON SECURESTRAP™ Open demonstrated significantly lower ratings in five of the six elements of surgical task load, namely – Mental Demand, Physical Demand, Situational Stress, Task Complexity, and Temporal Demand [p<0.05 for all] compared to suture fixation. **CONCLUSIONS:** Time for fixation and related surgical task load can be significantly reduced by using the ETHICON SECURESTRAP™ Open fixation device compared with suture fixation of IPOM mesh. This shows promise of reducing open IPOM procedure time which may realize related patient benefits of reduced anesthesia time, infection risks, costs etc. Also, reduction in surgical stress could potentially offer improvement in surgical performance – benefiting the surgeon, the patient and the health care system.

HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector

PHP198

COST SAVINGS IN THE HUNGARIAN CARE MANAGING PROGRAMME

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OBJECTIVES: A pilot care managing programme was introduced in Hungary in 1999. The conceptual foundations of the Hungarian implementation of managed care is closer to what was called the GP fundholding in the UK than HMOs in the USA. The purpose of the study is to analyse the cost savings realized within the Hungarian care managing programme. **METHODS:** The data derive from the financial database of the Hungarian National Health Insurance Fund Administration (NHIFA) covering the period 1999-2007. We identified the annual cost savings realized by the Care Managing Organizations. The Hungarian CMOs was financed through a risk adjusted capitation fee and the health services covered by CMOs were defined in legal regulations. Cost saving was defined as the difference between the annual revenues (capitation fee) and expenditures (real utilization) of care managing organizations. **RESULTS:** During the study period the total number of persons covered by the care managing programme increased from 1.5 % of the Hungarian population to its peak of 19.4 % in 2005. The cost saving of the care managing programme was 63138000 Hungarian Forint (HUF) or 249756 Euro (EUR) in 1999; 457662600 HUF (1759945 EUR) in 2000, 1109442300 HUF (4322246 EUR) in 2001; 2710926900 HUF (11157503 EUR) in 2002; 1452041100 HUF (5727683 EUR) in 2003, 3799000306 HUF (15094804 EUR) in 2004; 3709400000 HUF (14954510 EUR) in 2005; 4964600000 HUF (18786048 EUR) in 2006 and 3669000000 HUF (14599437 EUR) in 2007. These amounts resulted in the following annual savings rate: 1999: 3.6%; 2000: 10.4%; 2001: 6.5%; 2002: 8.7%; 2003: 3.4%; 2004: 4.0%; 2005: 2.1%; 2006: 2.9% and 2007: 2.9%. **CONCLUSIONS:** With the development of the Hungarian care managing system, the average number of enrolees increased. Cost savings of Care Managing Organizations varied between 2.1-4.0 % during the mature period of this programme.

PHP199

SYSTEMATIC REVIEW ON THE IMPACTS OF STRICT PHARMACEUTICAL PRICE CONTROLS

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OBJECTIVES: To systematically review and synthesize published evidence on the impact of pharmaceutical price controls, such as price cuts, price caps, price freezes or international price referencing. **METHODS:** A literature search was conducted in Medline, Scopus, Econlit, Web of Science and ABI/INFORM to identify relevant studies published in English to March 2013. **RESULTS:** Forty-seven out of 3787 initial studies were included. Price caps and price reductions were most commonly studied in the literature, followed by reference pricing and price freezes. The evidence indicates that price controls reduce company profits and have a detrimental effect on pharmaceutical research and development, pipeline productivity and investment. They may also inhibit, reduce or delay new product launches, increase parallel exports and diminish availability of generics due to disincentives and, hence, may reduce product availability, increase withdrawals and shortages. In terms of public expenditure about half of the studies indicate realized savings, but the other half indicate no effect or even increases in expenditure. In terms of effects on patients, studies indicate in the short term welfare gains due to lower cost and better access, but also losses due to drug shortages and availability issues. Long-term effects appear to be welfare losses due to reductions of discoveries, resulting from the disinvestment associated with the lower revenues. **CONCLUSIONS:** Effects of price controls are ambiguous in the case of pharmaceuticals. Price controls reduce drug acquisition cost and increase access in the short run. On the other hand, they may decrease patient welfare and access as they can cause product shortages, withdrawals and launch delays. Moreover, they may reduce the likelihood for new product discoveries. Contrary to common beliefs, price controls not always reduce expenditure. Thus careful consideration is needed in designing drug price policies. Value based pricing approaches may be more effective alternatives compared to price cutting.

PHP200

GUIDANCE FOR PARTNERSHIP WORKING BETWEEN CATSALUT AND THE PHARMACEUTICAL INDUSTRY

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OBJECTIVES: Relationships between National/Regional Health care Systems (NHS) and pharmaceutical companies can and should be based on a cooperative venture, built on the expertise of each side, that best meets clearly defined public needs through the appropiate allocation of resources, risks and rewards, while preserving transparency and its independence. However, joint working can be difficult to initiate due to the number of parties involved and the lack of clear shared objectives. Guidelines can be very useful to support the NHS/Pharmaceutical Partner's commitment. To our knowledge, there are no such published guidelines in Spain. This first guidance in Spain was designed with the main aim of identifying and simplifying the initiation, the start-up phase and the remainder of joint working projects between the Catalan Heath System (CatSalut) and pharmaceutical companies. **METHODS:** A flowchart was designed to describe the standard steps and timelines suggested to start, implement, monitor and evaluate a Joint Working pro-